UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
WESTERN DIVISION

JUDITH D. WALLS, et al.,]
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Plaintiff(s),]
]
vs.] CV-99-CO-02032-W
]
ALPHARMA USPD, INC., et al.,]
]
Defendant(s).]

MEMORANDUM OF OPINION

Judith Walls filed this action on behalf of herself and her daughter, Brittany Adams. The plaintiffs allege that Adams suffers from permanent injuries as a result of Walls' use of Alpharma's lindane 1% lotion while Walls was pregnant with Adams in 1986. This cause is before the Court for consideration of defendant Alpharma's motion for summary judgment, filed November 1, 2001, and motions to strike the affidavits of Thomas Mendelsohn and Mike Andrews. (Docs. 94, 97, 109.) The motions have been briefed and are ripe for decision. Upon due consideration, and for the reasons stated herein, the motion to strike the affidavit of Thomas Mendelsohn will be denied. (Doc. 97.) The motion to strike the affidavit of

Mike Andrews will be denied. (Doc. 109.) The motion for summary judgment will be granted in part and denied in part. (Doc. 94.)

I. The Motions to Strike.

A motion to strike is appropriate under Fed. R. Civ. P. 12(f) for "any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." *Id.* In addition, the power to strike a pleading is inherent in a trial court's authority to enforce its orders and ensure prompt disposition of legal actions. *State Exchange Bank v. Hartline*, 693 F.2d 1350, 1352 (11th Cir. 1982). A Rule 12(f) motion is addressed only to the pleadings and should not be used to object to an affidavit filed in support of a motion. *Smith v. Southeastern Stages, Inc.*, 479 F. Supp. 593, 594 -5 (N.D. Ga. 1977), citing Wright and Miller, Federal Practice & Procedures 1380. "It is sufficient for the party opposing the motion to register its objection to the movant's affidavits by way of the material submitted in opposition to the motion. The court will then implicitly, if not explicitly, rule upon these objections in its consideration of the motion." *Id.* Accordingly, the motions to strike will be denied. (Doc. 97, 109.)

However, Thomas Mendelsohn's statement that Revco purchased all of its generic lindane from Barre-National, is based on information given to him by Revco employees. (Mendelsohn Dep., pp. 37, 39-41.) This hearsay evidence will not be considered. The Court has concluded, as discussed below, that the plaintiffs presented sufficient evidence that Alpharma manufactured the drug in question to create a triable issue of fact without the need to consider this hearsay evidence or the additional evidence offered in the statements of Mike Andrews.

II. Summary Judgment Standard.

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The party moving for summary judgment "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying those portions of [the evidence] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). The movant can meet this burden by presenting

evidence showing that there is no genuine dispute of material fact, or by showing that the nonmoving party has failed to present evidence in support of some element of its case on which it bears the ultimate burden of proof. *Celotex*, 477 U.S. at 322-23. In evaluating the arguments of the movant, the court must view the evidence in the light most favorable to the nonmoving party. *Mize v. Jefferson City Bd. of Educ.*, 93 F.3d 739, 742 (11th Cir. 1996).

Once the moving party has met his burden, Rule 56(e) "requires the nonmoving party to go beyond the pleadings and by her own affidavits, or by the 'depositions, answers to interrogatories, and admissions on file,' designate 'specific facts showing that there is a genuine issue for trial.'" *Celotex*, 477 U.S. at 324 (quoting Fed. R. Civ. P. 56(e)). "A factual dispute is genuine only if a 'reasonable jury could return a verdict for the nonmoving party.'" *Info. Sys. & Networks Corp. v. City of Atlanta*, 281 F.3d 1220, 1224 (11th Cir. 2002) (quoting *United States v. Four Parcels of Real Property*, 941 F.2d 1428, 1437 (11th Cir. 1991)).

III. Facts.[1]

Except as noted, the parties agree upon the following pertinent facts:[2]

During 1986, Judith Walls was examined and treated by Dr. Cynthia Lucy, a Tuscaloosa dermatologist. Dr. Lucy knew that Ms. Walls was three months pregnant at the time she treated her. On or about June 26, 1986, Dr. Lucy diagnosed Ms. Walls and her then husband Alan Adams with scabies. On that same day, Dr. Lucy prescribed Eurax for both of them and provided Ms. Walls samples of Synalar, another prescription medication. The treatment was not successful for either of them and on or about July 2, 1986, Ms. Walls contacted Dr. Lucy by phone, who again instructed her and Mr. Adams to apply Eurax and also prescribed Synalar and Zone A lotion. Both continued to suffer from scabies and on July 10, 1986, Ms. Walls was again examined by Dr. Lucy. During that visit, Dr. Lucy prescribed 6%

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[1]In developing the statement of facts for this opinion, the Court considered the facts proposed by the parties and the Court's own examination of the record. All reasonable doubts about the facts have been resolved in favor of the nonmoving party. *See Info. Sys. & Networks Corp. v. City of Atlanta*, 281 F.3d 1220, 1224 (11th Cir. 2002). These are the "facts" for summary judgment purposes only. They may not be the actual facts. *See Cox v. Adm'r U.S. Steel & Carnegie Pension Fund*, 17 F.3d 1386, 1400 (11th Cir. 1994).

[2](Doc. 95, pp. 1-7; Doc. 118, pp. 1-5.)

precipitated sulfur and petroleum for Ms. Walls and wrote a prescription for lindane lotion only for Mr. Adams. That night, Mr. Adams applied lindane lotion to himself and Ms. Walls applied it to the portions of his body that he could not reach. Lindane cured Mr. Adams, but Ms. Walls still was not cured. So, on July 16, 1986, Dr. Lucy instructed Ms. Walls to use lindane 1% lotion from the prescription that had been written and filled for Mr. Adams. Dr. Lucy did not write a prescription for Ms. Walls and Ms. Walls did not return to the pharmacy to purchase any lindane for herself. Dr. Lucy instructed Ms. Walls to use the lindane at night and to wash it off in the morning. Dr. Lucy also informed Ms. Walls that the risks of using lindane lotion were "almost nothing" if she used it as it was prescribed and that the benefit of using lindane was that it was a "very effective treatment for scabies." Ms. Walls applied the lotion to her body and washed it off the following morning.

On January 21, 1987, Ms. Walls gave birth to Brittany Adams. Brittany suffers from mental retardation and disorders of the central nervous system. (Doc. 95, p. 4; Doc. 118, p. 3.)

Gamma Benzene Hexachloride, "GBH," was first approved by the Food and Drug Administration ("FDA") in 1952 for the treatment of lice and scabies. (Doc. 95, p. 4; Doc. 118, p. 3.) GBH is also known as lindane and was marketed by Reed & Carnrick under the brand name Kwell. On or about December 17, 1981, Barre-National obtained FDA approval to produce a generic brand of lindane lotion. By 1984, other companies were manufacturing and marketing GBH products. In October 1987, Alpharma purchased Barre-National and assumed its liabilities.[3]

Ms. Walls purchased all of the medicine described above from Revco Pharmacy at Bama Mall, Tuscaloosa, Alabama. (Doc. 95, p. 2; Doc. 118, p. 2.) Revco does not have a copy of the prescription it filled for Ms. Walls in July 1986 and does not have any knowledge regarding the companies from whom it purchased lindane lotion during the 1981-84 time frame, nor does Revco know who manufactured the lindane lotion it purchased during that time. (Doc. 95, p. 5; Doc. 118, p. 4.) Ms. Walls did not retain any of the product, packaging, or labeling that came with the product she used, nor

[3]In this opinion, Alpharma and Barre-National will be used interchangeably.

did she keep a copy of the prescription Dr. Lucy wrote. Her recollection about the product she used was:

> To the best of my recollection, the container looked brown in color, like a prescription cough medicine bottle, made of glass. The label had the name, date, doctor's name, Revco's name and phone number, Prescription number, Lindane Lotion - use as directed. Lindane lotion was a light milky looking liquid.

(Doc. 95, p. 5; Doc. 118, p. 4.) Ms. Walls testified the bottle had a white cap and did not have the word "Kwell" on the label. (Doc. 118, p. 4, citing Doc. 123, Pls' Ex. A, pp. 103, 116.)

Dr. Lucy does not know whether she prescribed brand name or generic lindane, but she frequently wrote prescriptions so that her patients could obtain either brand name or generic forms of medication. (Doc. 95, p. 2; Doc. 118, p. 2.) During the 1986 time frame, Dr. Lucy saw warning labels for lindane. (Doc. 95, p. 7; Doc. 118, p. 5.) Her knowledge concerning lindane was obtained through her residency training and from the Physician's Desk Reference ("PDR"), a standard tool used by doctors for information on medicine. During the 1986 time period, Dr. Lucy provided patients such as Ms. Walls the following precautions: ". . . we would tell people how to apply it and that it should be washed off in eight hours and

that there should not be repeat applications." She treated patients with scabies, including expectant mothers, during her residency and in so doing, utilized the same method of treatment as that which she used with Ms. Walls.

IV. Discussion.

Alpharma claims it is entitled to summary judgment because (1) Judy Wall's claims are time-barred; (2) the AEMLD claim is precluded by Alabama law; (3) the plaintiffs have no negligence claim; (4) there is no evidence plaintiffs used an Alpharma product; and (5) the plaintiffs cannot prove their injuries were caused by an Alpharma product. (Doc. 95.)

A. Plaintiffs's Evidence that an Alpharma Product Was Used.[4]

Alpharma argues it is entitled to summary judgment because there is no evidence that the lindane used by Ms. Walls during her pregnancy was an Alpharma product.

In an action under the Alabama Manufacturer's Extended Liability Doctrine ("AEMLD"), the plaintiff must prove that the defendant

[4]The Court directed the parties to submit supplemental briefs addressing the sufficiency of plaintiffs' evidence that an Alpharma product was used, and that issue will be addressed first.

manufactured or sold the defective product. *Turner v. Azalea Box Co.*, 508 So. 2d 253, 254 (Ala. 1987). The identity of the manufacturer of a defective product may be proven by circumstantial evidence. *Id.* However, "evidence which affords nothing more than mere speculation, conjecture or guess is wholly insufficient to warrant submission of the case to the jury." *Id.* (citations omitted). "When evidence points equally to inferences that are favorable and to inferences that are unfavorable to the moving party, the evidence lacks probative value; and the evidence may not be used to support one inference over another because such use is mere conjecture and speculation." *Id.*

There is evidence from which a reasonable jury could find: (1) in 1986, Walls purchased lindane lotion 1% solution from a Revco pharmacy; (2) her physician frequently wrote prescriptions so that a generic lotion could be dispensed;[5] and (3) Walls testified that the lotion was dispensed in a brown

[5]Dr. Lucy testified that she "usually" wrote her prescriptions so that patients could get a generic or a brand name, that it was "more than likely" the prescription was written so that a generic could be dispensed, and that her "routine" was to write prescriptions so as to permit a choice. (Doc. 96, Def. Ex. A, Lucy Dep., pp. 16, 27, 70-71.)

glass bottle with a white cap, the label said "Lindane Lotion," and the brand name "Kwell" was not on the bottle.

In addition, the plaintiff submitted deposition testimony and an affidavit of Thomas Mendelsohn, who, from 1985-87, was senior vice president of sales and marketing for Barre-National, the predecessor to Alpharma. Mendelson stated that during the 1980's, Barre-National had approximately 95% of the generic market for lindane shampoo and lotion. (Doc. 96, Def. Ex. L, Mendelsohn Affidavit.) He further stated that Barre-National was owned by Revco. *Id.* Mendelsohn testified that Revco purchased significant quantities of lindane lotion from Barre-National. (Doc. 123, Ex. E, p. 82).[6]

Thus, the plaintiffs have presented evidence from which a jury could reasonably find that Alpharma's predecessor, Barre-National, manufactured the generic lindane lotion Ms. Walls obtained from Revco in 1986. The evidence creates "more than an 'evenly balanced' likelihood," that Revco

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[6]As discussed previously, Mendelsohn's statement that Revco purchased 100% of its lindane lotion from Barre-National during the relevant period is hearsay because his knowledge came from Revco employees. However, as vice president of sales for Barre National, he is competent to testify that Revco purchased lindane from Barre-National.

purchased the generic lindane lotion from its wholly-owned subsidiary Barre-National, which manufactured 95% of all generic lindane lotion in 1986. *Foster Wheeler USA Corp. v. Owens-Illinois, Inc.*, 595 So. 2d 439, 441 (Ala. 1992); *See Azalea Box*, 508 So. 2d at 254 (rejecting showing that pointed equally to inferences that were favorable and unfavorable to the moving party). The *Azalea Box* Court relied on *Roberts v. Carroll*, 377 So. 2d 944, 946 (Ala. 1979), which is instructive on the holding:

> [T]he rule is well established that a directed verdict may not be given where the evidence is open to a reasonable inference of a material fact unfavorable to the moving party. . . . Stated another way, where a directed verdict is requested, the entire evidence must be viewed in a light favorable to the party opposing the motion, and it is only where the facts are such that reasonable men must draw the same conclusion from them that the issue becomes one of law for the court to determine; otherwise, the question is one of fact for determination by the trier of facts. . . . On the other hand, evidence which affords nothing more than mere speculation, conjecture, or guess is wholly insufficient to warrant submission of the case to the jury.

Id. (citations omitted); And see *Foster Wheeler*, 595 So. 2d 439 (Ala. 1992)(in maritime case, testimony that one manufacturer supplied most of asbestos-containing product, but two other manufacturers supplied some asbestos-containing products, failed to show that it was more probable that

first manufacturer's insulation material was installed on ship; even if manufacturer supplied 50% of material evidence would create, at best, 50-50 probability); *Sheffield v. Owens-Corning Fiberglass Corp.*, 595 So. 2d 443, 450 (Ala. 1992)(in maritime case, stating that plaintiff must make it appear that it is more likely than not that the product manufactured by defendant was a substantial factor in producing his injury under Section 433B of *Restatement (Second) of Torts*); *Strickland v. Royal Lubricant Co.*, 911 F. Supp. 1460, 1471 (M.D. Ala. 1995)(circumstantial evidence was of sufficient strength to connect the use of defendant's hydraulic fluid with helicopter that injured plaintiff).

B. Judith Wall's claims.

This Court has previously held that Judith Wall's claims are barred by the two year statute of limitations. July 10, 2001, Memorandum of Opinion, (Doc. 88.) The plaintiffs have provided no basis for revisiting that decision, and Alpharma's motion will be granted as to Judith Walls' individual claims.

C. The AEMLD Claim.

Alpharma contends Brittany's AEMLD "Failure to Warn" claim is precluded under Alabama law by the "learned intermediary" doctrine. As explained by the Alabama Supreme Court:

> In cases involving complex products, such as those in which pharmaceutical companies are selling prescription drugs, the learned intermediary doctrine applies. Under the learned intermediary doctrine, a manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of its product. This standard is 'an understandable exception to the Restatement's general rule that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products.' As such, we rely on the expertise of the physician intermediary to bridge the gap in special cases where the product and related warning are sufficiently complex so as not to be fully appreciated by the consumer.... 'Under the "learned intermediary doctrine" the adequacy of [the defendant's] warning is measured by its effect on the physician, ... to whom it owed a duty to warn, and not by its effect on [the consumer].'

Walls v. Alpharma USPD, Inc., 2004 WL 406759, *2 (Ala. 2004), quoting *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313-14 (11th Cir. 2000), (emphasis in original). "[W]hen the warning to the intermediary is inadequate or misleading, the manufacturer remains liable for injuries sustained by the ultimate user." *Porterfield v. Ethicon, Inc.*, 183 F.3d 464,

468 (5th Cir. 1999); *Timm v. Upjohn Co.*, 624 F.2d 536, 538 (5th Cir. 1980); *See Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301, 1204 (Ala. 1984).

The plaintiffs argue the learned intermediary doctrine does not apply without a doctor-patient relationship, so that Alpharma had a duty to warn persons who were not within a doctor-patient relationship but could foreseeably be exposed to lindane. As this Court observed in its June 24, 2004, opinion, the learned intermediary doctrine applies to all "ultimate consumers" and is an exception to the Restatement's "general rule that one who markets goods must warn foreseeable ultimate users." (Doc. 140, pp. 8-9.) In the case of prescription drugs, the duty to warn is satisfied by providing adequate warning to the prescribing physician.

The plaintiffs also argue that the learned intermediary doctrine does not apply because the only warning available was the Physician's Desk Reference warning for the brand-name "Kwell" lotion rather than Barre-National's generic lindane.[7] As discussed above, there is no dispute that Dr.

[7]Alpharma contends the FDA permits manufacturers of generic drugs to rely on the warnings provided by brand-name manufacturers.

Lucy was familiar with the PDR entry and was aware that it applied to lindane. (Doc. 118, p. 21, citing Dr. Lucy testimony, pp. 38, 44-45.) In *Tatum v. Schering Corp.*, 795 F.2d 925 (11th Cir. 1986), the Alabama federal district court granted summary judgment for the defendant drug manufacturer because the physician had knowledge independent of the manufacturer's warning, reasoning that there could be no causal link between a failure to advise the physician of what he already knew and the patient's injury. *Id.* at 927 (". . . on the question of causation it matters not where the knowledge came from"). The Eleventh Circuit agreed that, as to one of the claimed inadequacies, the physician had independent knowledge which was substantially the same as the knowledge the plaintiff claimed should have been communicated by the manufacturer, thus barring a conclusion of proximate cause. *Id.* at 928. *See Christopher v. Cutter Laboratories*, 53 F.3d 1184, 1192 (11th Cir. 1995)(applying Florida law).

Nevertheless, the plaintiffs also contend the PDR warning was inadequate.[8] In *Tatum*, the Eleventh Circuit agreed that the totality of the

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[8]The 1984, 1985, and 1986 PDR entry for Kwell provides, in pertinent part: "**Contraindications**: KWELL cream is contraindicated for individuals with known sensitivity to this product or to any of its components.

physician's knowledge was relevant, but it found summary judgment was improper as to three areas that were not embraced in the drug manufacturer's warning or the physician's independent knowledge. *Tatum*, 795 F.2d at 927-28. Here, the plaintiffs claim the lindane warning was inadequate because the PDR warning to "use with caution" in pregnant patients was vague. Plaintiffs point to Dr. Rasmussen's testimony that the phrase was undefined, and that the physician did not know, for example, whether to use less, wash it off sooner, not wash it off, keep it on the skin less often, or use gloves for application. (Doc. 118, p. 22-23, citing testimony of Dr. Rasmussen.) The adequacy of a warning is a question of fact for the jury. *Toole v. McLintock*, 999 F.2d 1430, 1433 (11th Cir. 1993, *citing State Farm Fire & Casualty Co. v. J. B. Plastics*, 505 So.2d 1223, 1227 (Ala. 1987). Alpharma argues that the warning was in compliance with FDA

> **Warning:** KWELL CREAM SHOULD BE USED WITH CAUTION, ESPECIALLY ON INFANTS, CHILDREN AND PREGNANT WOMEN. LINDANE PENETRATES HUMAN SKIN AND HAS THE POTENTIAL FOR CNS TOXICITY. STUDIES INDICATE THAT POTENTIAL TOXIC EFFECTS OF TOPICALLY APPLIED LINDANE ARE GREATER IN THE YOUNG. Seizures have been reported after the use of Lindane, but a cause and effect relationship has not been established. Simultaneous application of creams, ointments, or oils may enhance the percutaneous absorption of Lindane."

[1984, 1985, 1986 PDR]. (Doc. 96, Def. Ex. O, Physicians' Desk Reference, 1984-86.)

regulations, but it has not pointed to any case in which it was held that compliance with FDA regulations conclusively eliminated a manufacturer's liability. *See Foster v. American Home Prod. Corp.*, 29 F.3d 165 (4th Cir. 1994)(describing process for FDA approval of generic drug and concluding name brand manufacturer was not responsible to user of generic drug for inadequate warning); *and Medtronics v. Lohr*, 518 U.S. 470 (1996)(holding that preemption provision of Medical Device Amendment to the Food, Drug and Cosmetic Act does not preempt state common law claims for defective design, labeling and marketing).

D. The Negligence Claim.

Alpharma argues the negligence claim is subsumed by the AEMLD claim, citing *Rudd v. General Motors Corp.*, 127 F. Supp. 2d 1330 (M.D. Ala. 2001) and *Spain v. Brown & Williamson Tobacco Corp.*, 230 F.3d 1300 (11th Cir. 2000). After briefing was completed on the present motion, the Alabama Supreme Court answered certified questions for the Eleventh Circuit in the *Spain* litigation, stating that negligence and wantonness claims are viable alternatives to the AEMLD. *Spain v. Brown & Williamson Tobacco Corp.*, 872 So. 2d 101 (Ala. 2003).

E. Causation.

Alpharma argues that the plaintiffs cannot prove Brittany Adams' condition was caused by the lindane 1% lotion. Although Alpharma has filed motions to exclude the evidence from Dr. Jean Lauder, Dr. Alexandre Todorov, Dr. Rod O'Connor, and Dr. Kenneth R. Laughery (Docs. 98, 99, 100, 112), it has not challenged the report of toxicologist Richard A. Parker, Ph.D. (Doc. 123, Plaintiff's Ex. K). The Court has examined Dr. Parker's report and concludes it creates a triable issue of fact regarding causation. However, the Court anticipates it will have to reconsider this issue following the *Daubert* hearings.

V. Conclusion.

For the reasons discussed above, the motions to strike will be denied. (Doc. 97, 109). Judith Wall's individual claims will be dismissed, but the remainder of the motion for summary judgment will be denied. (Doc. 94.) A separate order will be entered.

Done, this 14th of October, 2004.

L. SCOTT COOGLER
UNITED STATES DISTRICT JUDGE